Medical Instruments Technology Inc.

Quality Reprocessing and Surgical Cost Containment Systems

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April 7, 2000

FDA Docket 00D-0053 Enforcement Document and Prioritization Scheme
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane (HFA-305)
Room 1061
Rockville, MD 20852

Dear Sir or Madam:

The following is Medical Instrument Technology, Inc.'s response to the FDA's Enforcement Document and Prioritization Scheme.

Infection Risk Categorization:

Medical Instruments Technology's position is that no device should be reprocessed that poses any increased safety or efficacy issues over the original manufactured device. We feel that success in reprocessing a device is based on validating the process to safety and efficacy end points that are substantially equivalent to the original product. The resulting reprocessed product becomes as good as new from a patient use standpoint.

End points for cleanliness and sterilization are well defined in ANSI/AAMI/ISO standards for medical device manufacturers. The only difference between cleaning and sterilizing a reprocessed device and an original device is the bioburden starting points. Cleaning and sterilization end points that have been tried and true over the years in the medical device industry also apply to reprocessed devices, e.g. the validated bioburden count must be low enough in both reprocessed and original devices so that the sterilization microbiological overkill of SAL of 10^{-6} is met.

The FDA's infection flow chart assumes that the difficulty to clean a device makes it a high risk. Difficulty to clean, however, is relative to the cleaning

00D-0053 C14

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method. Special proprietary cleaning technology has been developed that make it relative easy to meet the microbiological and sterilization safety end points for many so-called difficult-to-clean devices.

Based on these considerations, MIT recommends that the FDA's statement on difficulty of cleaning be changed to read "inability to clean to the microbiological bioburden count and sterilization SAL of 10^{-6} end points of the industry's consensus standards." All Single Use Devices (SUD) that pose no new safety or efficacy issues after cleaning and sterilization based on existing consensus standards should be considered low risk SUDs.

Consensus Performance Standards:

We agree that performance consensus standards for reprocesses device would be a very good idea. We also believe that performance standards for original devices would be a very good idea. The medical device industry has developed very few device performance standards since they were mandated in the 1976 Medical Device Amendment.

We feel that reprocessed devices should be held to the same performance standard criteria that apply to the original device manufacturers. MIT is willing to work on industry committees to develop performance standards that apply to both reprocessed and original devices. In the meantime, we believe that if the physical and functional characteristics of a reprocessed device can be demonstrated to be substantially equivalent to the original device, it poses no additional safety or efficacy risks to the patient than the original device.

Sincerely,

Jack R. Speer
President
Medical Instruments Technology, Inc

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